

## GCHHS ETHICS COMMITTEE CERIFICATE OF APPROVAL

Ms Lauren Heslop  
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**HREC Reference:** HREC/2021/QGC/75197  
**Project title:** An Occupational Therapy Pathway for Mild Traumatic Brain Injury ED presentations across the lifespan: A Non-Contemporaneous Cohort Comparison Study

Thank you for submitting the above-named project for ethical and scientific review, which was undertaken by the Gold Coast Hospital and Health Service Human Research Ethics Committee (HREC).

This research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)-Updated May 2018*.

HREC approval is valid for **3 years**. Expiry 6 August 2024

### Sites Approved

Gold Coast Hospital and Health Service
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Please note the following conditions of approval:

1. **This letter constitutes ethical approval only and is not authorisation to commence.** Please submit this letter to the Research Governance Officer (RGO) at any HHS study sites along with a completed Site-Specific Assessment (SSA) Form and relevant documents, for authorisation.
2. In accordance with the requirements of the *National Statement*, sections 2.3.9 - 2.3.10, the HREC **waived** the requirement for consent for the collection, use and/or disclosure of personal information in medical research or personal health information for the research project listed.
  - a. Please consider permissions under the *Hospital and Health Boards Act 2011* or *Public Health Act 2005* to enable access to confidential information for the purposes of research without consent. If you are unsure which permissions to use you should contact the local Research Governance Officer at the site/s where the research will be conducted.
2. **Reporting to HREC:** The following reports are required by the HREC. Failure to report may result in withdrawal or suspension of HREC approval:
  - i. **Annual Progress Reports:** Progress reports are due by **30 April each year**.

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- ii. **Other monitoring:** The GCHHS administration and/or HREC may inquire into the conduct of any research being conducted on GCHHS premises or claiming any association with GCHHS; or which the Committee has approved.
3. **Is your project GCP ready?** Step-by-step GCP-ready checklists to guide how to implement GCP throughout your project are available to Allied Health staff for different research designs linked here: [prospective intervention studies](#), [observational or retrospective research \(e.g., chart audits\)](#) and [qualitative designs](#). The Allied Health Services Research Team also offer **supportive GCP check-ups** to Allied Health staff to support implementing GCP principles in ethically-approved projects: email [AlliedHealthResearchGCH@health.qld.gov.au](mailto:AlliedHealthResearchGCH@health.qld.gov.au).
  4. **Amendments:** Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Please provide the rationale for the amendment and track changed documents where applicable. These must be submitted via a PAN form in ERM.
  5. **Early termination/ routine completion of the project:**
    - a. Please notify the HREC if the project is discontinued at any site prior to completion.
    - b. For projects that are completed, submit a progress report with a copy of any research summaries or intended publications.
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## APPROVED DOCUMENTS

*It is the Coordinating Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved:*

APPROVED DOCUMENTS	Version	Version date
HREC application	1	14 April 2021
Response to request for further information		14 July 2021
Study Protocol	2	5 July 2021
Participant Information and Consent Form. Prospective (Adult)	2	12 July 2021
Participant Information and Consent Form. Prospective (Child)	2	12 July 2021
Participant Information and Consent Form. Retrospective (Adult)	2	12 July 2021
Participant Information and Consent Form. Retrospective (Child)	2	12 July 2021
Data collection and script. Prospective	2	12 July 2021
Data collection and script. Retrospective	1	April 2021
Patient Experience Survey. Prospective	1	14 April 2021
Patient Experience Survey. Retrospective	1	30 March 2021
Participant Letter/Email	1	April 2021

Letter of invitation for adult participants for cohort 1	1	12 July 2021
Letter of invitation for parent or guardian for Cohort 1	1	12 July 2021
Email of invitation for staff participants	1	12 July 2021
Staff Participant Information and Consent Form	1	April 2021
Staff Participant Interview Script	2	12 July 2021
World Health Organization Disability Assessment Schedule 2.0	Adult	© 2010
WHODAS 2 Children and Youth 36-Item Version	-	© 2010
ED and Occ Thy mTBI pathway Flowchart	1	12 April 2021
Rivermead Post Concussion Symptoms Questionnaire	-	© 1995
WHODAS email permission for copyright material	377403	23 March 2021

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*, *NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2018)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. The GCHHS HREC has been certified by the NHMRC to review multi centre research.

The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from [http://www.health.qld.gov.au/ohmr/html/regu/regu\\_home.asp](http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp)

The HREC wishes you and your colleagues every success in your research.

DocuSigned by:  
  
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Vanessa Druett  
 Research Ethics and Governance Lead  
 On behalf of  
**Dr Helen Green, Chairperson**  
 Gold Coast Hospital and Health Service Human Research Ethics Committee (EC00160)

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*Attached: HREC membership composition*